

authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 8, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-14624 Filed 6-16-10; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control/Initial Review Group, (NCIPC/IRG)

Correction: This notice was published in the **Federal Register** on February 18, 2010, Volume 75, Number 32, page 7284. The notice should read as follows:

NCIPC/IRG Workgroup: Research Grants for Preventing Violence and Violence-Related Injury, Funding Opportunity Announcement CE10-005.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned review group:

Times and Dates:

8 a.m.–5 p.m., March 11, 2010 (Closed)

8 a.m.–5 p.m., March 12, 2010 (Closed)

Place: JW Marriott Hotel Buckhead, 3300 Lenox Road, Atlanta, Georgia 30326, Telephone (404) 262-3344.

Status: This meeting was closed to the public in accordance with provisions set forth in 41 CFR part 102 of the General Services Administration Federal Advisory Committee Management Final Rule.

Matters to be Discussed: The meeting included the review, discussion, and evaluation of applications intended to expand and advance the understanding of violence, its causes, and prevention strategies. Requests for Applications are related to the following individual research announcement: CE10-005.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: J. Felix Rogers, PhD, M.P.H., NCIPC/ERPO, CDC, 4770 Buford Highway, NE., M/S F63, Atlanta, Georgia 30341-3724, Telephone (770) 488-4334.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 8, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control/Initial Review Group, (NCIPC/IRG)

Correction: This notice was published in the **Federal Register** on February 1, 2010, Volume 75, Number 20, pages 5089-5090. The notice should read as follows:

NCIPC/IRG Workgroup: Preventing Unintentional Childhood Injuries (R21), Funding Opportunity Announcement CE10-001.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned review group:

Time and Date: 12:30 p.m.—4 p.m.,

February 16, 2010 (Closed).

Place: Teleconference.

Status: This meeting was closed to the public in accordance with provisions set forth in 41 CFR part 102 of the General Services Administration Federal Advisory Committee Management Final Rule.

Matters To Be Discussed: The meeting included the review, discussion, and evaluation of cooperative agreement applications submitted in response to Fiscal Year 2010 Requests for Applications related to the following individual research announcement: CE10-001.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: J. Felix Rogers, PhD, M.P.H., Telephone (770) 488-4334, NCIPC/ERPO, CDC, 4770 Buford Highway, NE., M/S F63, Atlanta, Georgia 30341-3724.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 8, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-14622 Filed 6-16-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0291]

Converged Communications and Health Care Devices Impact on Regulation; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) and the Federal Communications Commission (FCC) are jointly sponsoring a public meeting entitled “Enabling the Convergence of Communications and Medical Systems: Ways to Update Regulatory and Information Processes.” The purpose of this meeting is to identify the challenges and risks posed by the proliferation of new sophisticated medical implants and other devices that utilize radio communications to effectuate their function, as well as challenges and risks posed by the development and integration of broadband communications technology with healthcare devices and applications. While the general format for this meeting is outlined in this document, the details will be further informed by the comments received, and a final agenda will be published on the Internet in the future.

Dates and Times: The public meeting is scheduled for July 26 and 27, 2010, from 8 a.m. to 5:30 p.m. Persons interested in attending and/or participating in the meeting must register by 5 p.m. EDT on July 19, 2010. Submit either electronic or written comments related to the agenda, by 5 p.m. EDT on June 25, 2010. All other comments must be submitted by August 16, 2010.

Location: The public meeting will be held at the FCC Commission Meeting Room, 445 12th St. SW., Washington, DC 20554.

Contact Persons: Bakul Patel, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 3543, Silver Spring, MD 20993, 301-796-5528, email:

bakul.patel@fda.hhs.gov; or Bruce Romano, Federal Communications Commission, 445 12th St. SW., rm. 7-C140, Washington, DC 20554, 202-418-2470, email: bruce.romano@fcc.gov.

Registration and Requests for Oral Presentations: Registration requests must be received by 5 p.m. EDT on July

19, 2010. Interested persons may register by emailing FCC-FDAMeeting@fcc.gov. Registrants must provide the following information: (1) Name, (2) title, (3) company or organization, (4) mailing address, (5) telephone number, and (6) email address. Registrants will receive confirmation once they have been accepted. Persons interested in attending the meeting are encouraged to register as registrants will have seating priority in order of registration and can be best assured of receiving information by email regarding any changes that may occur in meeting particulars. Also, registration will be required for all speakers. Overflow rooms with closed circuit video monitors will be provided as needed to accommodate the public. FDA and FCC may limit the number of registrants from each organization based on space limitations.

If you wish to make an oral presentation during any of the open comment sessions at the meeting, you must indicate this at the time of registration. FDA and FCC have included specific questions for comment in section III of this document. You should also identify which discussion topic you wish to address in your presentation. In order to keep each open comment session focused on the topic at hand, each oral presentation should address only the topic specified for that session. FDA and FCC will do their best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA and FCC will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you need special accommodations due to a disability, please send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (TTY) at least 7 days in advance of the meeting.

Comments: FDA and FCC are holding this public meeting to gather information on a number of questions regarding challenges and safety for patients and other users of medical devices that include radio elements and of systems that can be tied into broadband communication networks. The deadline for submitting comments related to the agenda is 5 p.m. EDT on June 25, 2010. The comment period for this public meeting closes on August 16, 2010.

Regardless of attendance at the public meeting, interested persons may submit

electronic comments to <http://www.regulations.gov>, or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and to the Federal Communications Commission, Office of the Secretary, 445 12th St. SW., rm. TW-A235, Washington, DC 20554. Send one paper copy of mailed comments if you are submitting to FDA and two paper copies of mailed comments if you are submitting to FCC, except that individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document (use docket number ET 10-120 for written submissions to FCC). In addition, when responding to specific questions as outlined in this document, please identify the question you are addressing. Received comments are available at all times via the Federal eRulemaking Portal: <http://www.regulations.gov>. They may also be seen in FDA's Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday or at the Federal Communications Commission, Reference Information Center, 445 12th St. SW., rm. CY-A257, Washington, DC 20554, Monday through Thursday between 8 a.m. and 4:30 p.m. and on Fridays between the hours of 8 a.m. and 12 noon.

SUPPLEMENTARY INFORMATION:

I. Background

There have been significant developments in recent years in medical and health care devices using radio technology to monitor various body functions and conditions, including critical elements, and to deliver treatment and therapy. There has also been an increasing proliferation of devices using established commercial communications networks such as Internet connectivity to communicate with care providers. Mobile devices like smartphones and personal digital assistants (PDAs) are transforming the transmission of information used by physicians to help manage patient care, including communication networks to relay information for patient health monitoring and decision support.

Examples of the latest implant or body-worn monitoring, therapeutic, and treatment technologies include blood glucose monitors and automated insulin pumps, heart monitors, pacemakers, defibrillators, and neural pathway replacements that stimulate muscle movement.

Examples of devices and applications that use commercial communications networks and represent the convergence

of communications and medicine include a smartphone application that displays real-time fetal heartbeat and maternal contraction data allowing obstetricians to track a mother's labor and wearable wireless patch-like sensors that transmit health data over commercial wireless networks to practitioners, caregivers, and patients.

These and other products cover a broad range of health care solutions. At one end, general-purpose communications devices such as smartphones, wireless routers and certain video-conferencing equipment are regulated by FCC. At the other end, medical devices that critically monitor patient health or provide treatment or therapy are regulated by FDA. Devices that do provide critical care and also use communications, such as life-critical wireless devices like remotely controlled drug-release mechanisms, are regulated by both agencies. In addition, device applications that would not be governed by FCC but transmit over wireless networks might warrant FDA oversight, while FCC might have better capability to assess the reliability of their communications capability.

The objective of this meeting is to gather information and to better understand issues and perspectives from various stakeholders so the Agencies can identify potential areas where each Agency's jurisdiction can be identified and clarified for affected parties, collection and assessment of each Agency's respectively appropriate information can be improved, expertise can be shared, and regulatory approval can be coordinated and simplified. These concerns relate both to devices operating on designated frequencies and to convergent medical device and information technology, as described previously. This includes challenges faced by manufacturers and innovators in ensuring compliance with various regulatory requirements and risks associated with medical device systems using spectrum shared by other medical devices, using spectrum shared by other types of devices and services, and using broadband communication capabilities.

FDA and FCC recognize the need to work with all stakeholders to identify pathways and strive to improve processes that will help continue to spur innovation in these areas while maintaining safety and effectiveness and promoting public health.

II. Public Meeting

The information gathered during the meeting will be used to enhance the coordination between FDA and FCC for such devices and applications, and clarify and delineate the respective

areas of expertise and jurisdiction between the Agencies. This information will simplify and expedite the introduction of new and important medical technologies and techniques while maintaining safety and efficacy levels appropriate to the various technologies and devices.

During each session, members of the public may present oral comments related to the topic of that session. Specific questions for comment are listed in section III of this document. Individuals who are interested in giving an oral presentation during any of the sessions must indicate this interest at the time of registration and must also identify the session(s) at which they would like to present (see *Registration and Requests for Oral Presentation*). In order to keep each session focused on the topic at hand, each oral presentation should address only the topic specified for that session. Persons who wish to comment are free to submit written comments on any topic(s) to the open docket (see *Comments*). FDA and FCC will schedule speakers for each session as time permits.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule for each session, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at <http://www.regulations.gov> and in the FDA and FCC public reference rooms listed previously. This information will also be available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list) and from <http://www.fcc.gov/workshops>.

III. Questions for Comment

FDA and FCC are planning to focus the public meeting on the following topics:

1. Data integrity and reliability issues arising from the use of allocated spectrum, the use of unlicensed devices, and the use of commercial networks and applications, and needs, uses, and risks for 'medical-grade' wireless technology and communications.

2. Medical device and system security issues—inadvertent and intentional intrusion—nonfunction and malfunction.

3. Trends in medical devices using allocated spectrum and using unlicensed operation, and medical devices and applications using commercial networks. Consideration of various wireless networking scenarios and use cases.

4. Risks Management:

- The need to define levels of "criticality" of device function that can be used for determining reliability requirements.

- Environmental factors and delivery setting—hospitals, users, clinics, home, travel, etc.

5. Views on current FDA and FCC regulatory requirements:

- Relationship between FDA approval/clearance and FCC certification of applications, post market and compliance requirements.

Each of the previous topics will cover:

1. Defining topics and scope;
2. Identifying the needs, goals, and stakeholders; and
3. Recommendations.

FDA and FCC are seeking comments on the topics and soliciting suggestions on alternate or additional topics that commenters deem closely related. All comments and suggestions will be considered with the constraint of completing the workshop in no more than 2 days. To be considered, topics proposed must be relevant to the objective and intent of the workshop.

IV. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857 or at the Federal Communications Commission, Reference Information Center, 445 12th St. SW., rm. CY-A257, Washington, DC 20554, Monday through Thursday, between the hours of 8 a.m. and 4:30 p.m. and on Fridays between 8 a.m. and 12 noon, approximately 15 working days after the public meeting at a cost of 10 cents per page. A transcript of the public meeting will be available on the Internet at <http://www.regulations.gov>.

Dated: June 14, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010-14687 Filed 6-14-10; 4:15 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Effectiveness Research on Smoking Cessation in Hospitalized Patients.

Date: June 22-23, 2010.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Shelley S. Sehnert, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892-7924. 301-435-0303. ssehnert@nhlbi.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 11, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-14648 Filed 6-16-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract